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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,705	02.06.2001	Karl Guegler	CLOO1010	5353

25748 7590 08.13.2002

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EXAMINER

BUNNER, BRIDGET E

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/13/2002 /O

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/776,705	GUEGLER ET AL.
	Examiner Bridget E. Bunner	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 July 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2 and 20-21, drawn to an isolated peptide set forth in SEQ ID NO: 2, classified in class 530, subclass 350.
 - II. Claim 3, drawn to an isolated antibody that selectively binds to a peptide, classified in class 530, subclass 387.9.
 - III. Claims 4-5, 8-11, and 22-23, drawn to an isolated nucleic acid molecule that encodes the peptide set forth in SEQ ID NO: 2, vector, host cell, and method of recombinant protein expression, classified in class 536, subclass 23.5.
 - IV. Claim 6, drawn to a gene chip comprising a nucleic acid molecule, classified in class 435, subclass 6.
 - V. Claim 7, drawn to a transgenic non-human animal comprising a nucleic acid molecule, classified in class 800, subclass 14.
 - VI. Claims 12, drawn to a method for detecting the presence of any peptide in a sample, classified in class 435, subclass 7.1.
 - VII. Claim 13, drawn to a method for detecting the presence of a nucleic acid molecule in a sample, classified in class 435, subclass 6.
 - VIII. Claims 14-15, drawn to a method for identifying a modulator of a peptide comprising contacting the peptide with an agent and determining if said agent has modulating the function or activity of said peptide, classified in class 435, subclass 7.1, for example.
 - IX. Claim 16, drawn to a method for identifying an agent that binds any peptide comprising contacting the peptide with an agent and assaying the contacted mixture to determine whether a complex is formed with the agent bound to the peptide, classified in class 435, subclass 4, for example.
 - X. Claim 17, drawn to a pharmaceutical composition comprising an agent identified in a binding assay and a pharmaceutically acceptable carrier, classification dependent upon structure of agent.

- XI. Claim 18, drawn to a method for treating a disease or a condition mediated by a transporter protein comprising administering to a patient a pharmaceutically effective amount of an agent, classification dependent upon structure of agent.
- XII. Claim 19, drawn to a method for identifying a modulator of the expression of a peptide comprising contacting a cell expressing said peptide with an agent and determining if said agent has modulated the expression of said peptide, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

- a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-III, V, and X are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group I can be prepared by processes which are materially different from recombinant DNA expression of Group III, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group III can be used other than to make the protein of Group I, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group I can be used in materially different methods other than to make the antibody of Group II, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group II can be used to obtain the DNA of Group III, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The pharmaceutical agent of Group X has a different structure and function than the products of Groups I-III and V and may be used in materially different methods, such as cell proliferation assays or therapeutic methods. Furthermore, the polypeptide and polynucleotide sequences of Groups I and III are each unique sequences from one another, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would

provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches. The transgenic animal of Group V is structurally different than the products of Groups I-III and X, and can be utilized for *in vivo* diagnostic or treatment protocols.

- b. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions IV, VI-IX and XI-XII are different methods because they require different ingredients, process steps, and endpoints. Groups IV, VI-IX and XI-XII are different methods requiring different method steps, wherein each is not required, one for another. For example, Group IV requires search and consideration of placing a nucleic acid molecule of interest onto a chip, which is not required by the other inventions. Group VI requires search and consideration of detection of a polypeptide in a sample, which is not required by the other inventions. Group VII requires search and consideration of detection of a nucleic acid molecule in a sample, which is not required by the other inventions. Group VIII requires search and consideration of identification of a peptide modulator by contacting the peptide with an agent and determination of alterations in peptide function or activity, which is not required by the other inventions. Group IX requires search and consideration of screening for agents that bind a peptide and measurement of the formation of peptide-agent complexes, which is not required by the other inventions. Group XI requires search and consideration of efficacy of treatment of a disease or condition mediated by a human protease by administration of an agent, which is not required by the other inventions. Group XII requires search and consideration of screening for agents that modulate peptide expression by contacting a cell expressing the peptide with an agent and measurement of alterations in peptide expression, which is not required by the other inventions.

- c. Inventions I and VI/VIII/IX/XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used as an antigen for the production of antibodies.
- d. Inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in a materially different processes, such as immunoassays or diagnostic assays.
- e. Inventions III and IV/VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as DNA purification and gene therapy.
- f. Inventions I and IV/VII/XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups I and VII/XI are unrelated product and methods, wherein each is not required, one

for another. For example, the claimed methods of Inventions IV, VII and XI do not recite the use or production of the polypeptide of Invention I.

- g. Inventions II and IV, VI-IX, XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups II and IV, VI-IX, XI-XII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IV, VI-IX, XI-XII do not recite the use or production of the antibody of Invention II.
- h. Inventions III and VI, VIII-IX, XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups III and VI, VIII-IX, XI-XII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI, VIII-IX, XI-XII do not recite the use or production of the nucleic acid molecule of Invention III.
- i. Inventions V/X and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups V/X/XIII/XIV and IV are unrelated products and method, wherein each is not required, one for another. For example, the claimed method of Inventions IV does not recite the use or production of the products of Inventions V/X/XIII/XIV.
- j. Inventions V and VI-IX, XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups V and VI-IX, XI-XII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI-IX, XI-XII do not recite the use or production of the transgenic non-human animal of Invention V.

- k. Inventions X and VI/VII/VIII/IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups X, XIII, XIV and VI/VII/VIII/IX are unrelated products and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI/VII/VIII/IX do not recite the use or production of the products of Inventions X, XIII, XIV.
2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate search requirements, different classification, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BEB
Art Unit 1647
August 8, 2002

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